Note: This is a template, *edit/modify* as appropriate. *Delete* instructional verbiage.

INFORMATION PROTECTED BY THE PRIVACY ACT OF 1974
(If applicable, keep. If not applicable, delete. If you are collecting PII – it is applicable)

Informed Consent Document
For
Title of Investigation

Organization/Office Symbol, Institution, Location

Principal Investigator: Rank/Name, DSN 000-0000, Organization/Office Symbol
Email address

Associate Investigators: Rank/Name, DSN 000-0000, Organization/Office Symbol
Email address

Rank/Name, DSN 000-0000, Organization/Office Symbol
Email address

Ensure emails/phone numbers are current

1. **Nature and purpose:** You have been offered the opportunity to participate in the "Title of Investigation" research study. Your participation will occur at the location.

   The purpose of this research is to evaluate...

   The time requirement for each volunteer subject is anticipated to be a total of "x" visits of approximately "x" minutes/hour(s)/day(s) each. A total of approximately "x" subjects will be enrolled in this study.

2. **Experimental procedures:** If you decide to participate...

3. **Discomfort and risks:** Discomforts may consist of…Potential risks include...If it is included in the protocol, it must be included in the consent form.

4. **Precautions for female subjects or subjects who are or may become pregnant during the course of this study:** Describe any additional precautions that may apply. If there are any. For Greater than Minimal Risk protocols, consider adding the following verbiage. If you are female or if you are pregnant, or may become pregnant during the course of this study, you must read and sign the Briefing Addendum for Female Subjects prior to making a decision to consent to become a subject in this research study.

5. **Benefits:** You are not expected to benefit directly from participation in this research study. If there is direct benefit to your subject, discuss.

6. **Compensation:** If you are active duty military you will receive your normal active duty pay. If there is any compensation to any subject discuss source of funds.

7. **Alternatives:** Your alternative is to choose not to participate in this study. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Notify one of the investigators of this study to discontinue.

8. **Entitlements and confidentiality:**

   a. Records of your participation in this study may only be disclosed according to federal law, including the Federal Privacy Act, 5 U.S.C. 552a, and its implementing regulations and the Health Insurance Portability and Accountability Act (HIPAA), and its implementing regulations, when applicable, and the Freedom of Information Act, 5 U.S.C. Sec 552, and its implementing regulations when applicable. Discuss how the data will be maintained. Use verbiage as applicable, add/delete to modify as applicable. Your personal information will be stored in a locked cabinet in an office that is locked when not occupied. Electronic files containing your personal information will be password protected and stored only on a secure server. It is intended that the only people having access to your information will be the researchers named above and this study's Medical Monitor or Consultant, the AFRL Wright Site IRB, the Air Force Surgeon General's Research Compliance office, the Director of Defense Research and Engineering office or any other IRB involved in the review and approval of this protocol. Add any other entities (e.g., IRB, research collaborators, etc) that will have access to the data.When no longer needed (identify timeline and reasoning) for research purposes your information will be destroyed in a secure manner (e.g., explain **exactly** what the destruction method will be for hard copy, electronic files, video/audio recordings and biospecimens). Complete confidentiality cannot be promised, in particular for military personnel, whose health or fitness for duty information may be required to be reported to appropriate medical or command authorities. If such information is to be reported, you will be informed of what is being reported and the reason for the report.

   b. Your entitlements to medical and dental care and/or compensation in the event of injury are governed by federal laws and regulations, and that if you desire further information you may contact the base legal office (711 HPW/JA, 986--5666 for Wright-Patterson AFB). In the event of a research related injury, you may contact the medical monitor, Rank/Name, of this research study at (000) 000-0000.

   c. **Include only in Greater than Minimal Risk protocols:** If an unanticipated event (medical misadventure) occurs during your participation in this study, you will be informed. If you are not competent at the time to understand the nature of the event, such information will be brought to the attention of your next of kin or other listed emergency contact.

Emergency contact information:

Name_____ Phone#_____

d. The decision to participate in this research is completely voluntary on your part. No one may coerce or intimidate you into participating in this program. Participate only if you want to. Rank/Name, or an associate, has adequately answered any and all questions you have about this study, your participation, and the procedures involved. If you have any further questions, Rank/Name can be reached at (000) 000-0000. Rank/Name, or an associate will be available to answer any questions concerning procedures throughout this study. If significant new findings develop during the course of this research, which may relate to your decision to continue participate or may affect the risk involved, you will be informed. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. Notify one of the investigators of this study to discontinue. Additionally, the investigator or medical monitor of this study may terminate your participation in this study if she or he feels this to be in your best interest. If you have any questions or concerns about your participation in this study or your rights as a research subject, please contact Kim London at (937) 656 – 5688 or kim.london.1@us.af.mil.

e. **Include only if applicable, otherwise delete.** Also, please note that if this is not applicable, delete the Privacy Act Statement at footer and header. Personal Identifiable Information to be obtained for this study include (specify exactly what information is going to be obtained for use or disclosure in the course of the study). Signing this document in no way alters your ability to obtain medical treatment that is not part of this study. Any Private Health Information obtained in the course of this study may be used by the investigator unless you revoke authorization to do so *in writing*. If your data is disclosed by the investigator to one of the parties listed above, those parties may pass on your data without further notification to you. Data collected in the course of this study may be withheld from you by the investigator for the duration of the study. If withheld, your data will be released (input the time of release, i.e. at the conclusion of the study, in X years, etc).

f. **Include only if applicable, otherwise delete.** Your participation in this study may be photographed, filmed or audio/videotaped. The purpose of these recordings is (describe specifically the **purpose** and **audience**).

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE. YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO PARTICIPATE HAVING READ THE INFORMATION PROVIDED ABOVE.

SUBJECTS MUST SIGN **PRIOR** TO PARTICIPATION.

THE VARIOUS FEDERAL LAWS APPLYING TO HUMAN SUBJECT RESEARCH REQUIRE THAT THE RESEARCH SUBJECT SIGN THIS CONSENT DOCUMENT. IN ADDITION, THE SUBJECT SHALL BE GIVEN A COPY OF THIS INFORMED CONSENT DOCUMENT FOR HIS/HER USE.

Volunteer Signature_____**Date**_____

Volunteer Name (printed)_____

Advising Investigator Signature _____ **Date** _____

Investigator Name (printed)_____

Witness Signature _____**Date** _____

Witness Name (printed)_____

Include only if there will be public release of the video/audio.We may wish to present some of the video/audio recordings from this study at scientific conventions or use photographs in journal publications. If you consent to the use of your image for publication or presentation in a scientific or academic setting, please sign below.

Volunteer Signature_____**Date**_____

Privacy Act Statement

Authority: We are requesting disclosure of personal information.. Researchers are authorized to collect personal information on research subjects under The Privacy Act-5 USC 552a, 10 USC 55, 10 USC 8013, 32 CFR 219, 45 CFR Part 46, and EO 9397, November 1943.

Purpose: It is possible that latent risks or injuries inherent in this experiment will not be discovered until some time in the future. The purpose of collecting this information is to aid researchers in locating you at a future date if further disclosures are appropriate.

Routine Uses: Information may be furnished to Federal, State and local agencies for any uses published by the Air Force in the Federal Register, 52 FR 16431, to include, furtherance of the research involved with this study and to provide medical care.

Disclosure: Disclosure of the requested information is voluntary. No adverse action whatsoever will be taken against you, and no privilege will be denied you based on the fact you do not disclose this information. However, your participation in this study may be impacted by a refusal to provide this information.